Utah Department of Health

# CLINICAL LABORATORY BULLETIN February 2007

**Web page: http://health.utah.gov/lab/labimp**

❖ INTRODUCING:

| | |
|---|---|
| Kristin Colton | Lab Improvement |
| Selvan Lingam | Toxicology |

## NOTEWORTHY

✓ **Quality Test Results:** Debbie Tiffany, MSEd, MT(ASCP), SC, SLS wrote an article for the Nov/Dec 2006 ASCLS newsletter entitled "The Five Rights of Safe Laboratory Testing". She list the five rights as:
**Right Patient:** 160,900 adverse patient events occurred per year due to patient mis-identification.
**Right Specimen:** use a clear-cut specimen rejection policy to assure quality samples.
**Right Method:** to select the best test method, review proficiency testing peer data. Validate an unapproved specimen type for your test method (i.e. using a urine dipstick to check for occult blood in a breast discharge).
**Right Personnel:** perform a "real" competency check.
**Right Improvement Strategy:** ideally learn from all errors and improve the process to prevent further errors. Create an *improvement* **not** *blame* culture.

✓ **Spin Time Critical for Stat Chemistry Tests:** Researchers at the Verona University of Studies in Italy reported a study they performed to detect the effect of centrifugation time on obtaining a quality sample for clinical chemistry analytes. They used five evacuated tubes collected from 10 consecutive persons. They used a swing bucket centrifuge at 1,200 *g* for 1, 2, 5, 10 and 15 minutes respectively. The authors conclude "We confirm that a 10-minute centrifugation time at 1,200 on a swing bucket centrifuge for samples collected in plastic tubes with a plasma separator may be suitable for stat clinical chemistry testing.

See the entire article in the March 2007 issue of Lab Medicine at www.labmedicine.com.

✓ **Identifying Resistant Staph:** Check the latest Clinical and Laboratory Standards Institute (CLSI) susceptibility document to make certain you use an adequate method to determine resistant staphylococci. For example – use a 30 *u*g cefoxitin disk (not oxacillin) on Mueller Hinton agar to detect methicillin resistance.

Automated susceptibility systems still miss a significant number of resistant organisms. In 2006 CLSI update there are new breakpoint ranges listed. These ranges are based on failed vancomycin therapy.

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2 *u*g/mL = susceptible
4-8 *u*g/mL = intermediate (VISA)
16 *u*g/mL = resistant (VRSA)

✓ **Urine pregnancy test kits – know the limitations:** There are innumerable types of CLIA "waived" urine pregnancy kits available. Many can be used on urine or serum (of course using serum changes the CLIA complexity status to "moderate"). While pregnancy is the most likely diagnosis when the hCG test is positive, its not the only possibility. Positive test results can come from other rare conditions such as ectopic pregnancy, molar pregnancy, trophoblastic and non-trophoblastic diseases, choriocarcinoma, etc. A well publicized false positive case involved a serum *B*-hCG result. The patient's final diagnosis was a rare form of cancer. She suffered needless surgeries and chemotherapy for 3 years. If the laboratory had been aware of the method limitations (human anti-mouse antibody was interfering – causing false agglutination) and performed a urine test when the woman was found not to be pregnant, the correct diagnosis would have saved a $16 million lawsuit award.

✓ **Specimen integrity essential for accurate BNP determinations:** Correctly identifying the cause of "chest pain" in the emergency department (ED) is often a life-threatening dilemma. BNP (brain natriuretic peptide) is a very popular screening test for ventricular wall stress to aid myocardial infarction detection.

Test methodologies are variable. Their cut-off points and reference ranges are patient population-dependant as well as method dependant. Validation practices should include both these variables. Once your method is ready, look at the patient's sample. Unless the assay you use is validated for glass tubes, collect specimens in plastic EDTA tubes. If your method does not specify otherwise, you should analyze the sample within 4 hours at room temperature or use one stored with a suitable additive.

✓ **Hemoglobin A1c (glycohemoglobin):** Nearly all clinicians monitor their diabetic patients with a quarterly Hemoglobin A1c (Hb A1C) test. The test has proven an effective long-term glucose control mechanism. The American Diabetes Association recommends keeping diabetics at <7%. Even compliant diabetics with stable glucose levels should be tested twice a year. Many conditions can interfere with accurate Hb A1C test results. Check your method's package insert for interfering substances such as:

Alcoholism
Drugs / vitamins
Hematuria
Hyperbilirubinemia
Hyperglycemia (marked)
Hypertension (marked)
Hypertriglyceridemia
Iron deficiency anemia
Lead poisoning
Lipemia
Other types of hemoglobin (HgbS or HgbC)
Process that could decrease the red blood cell (RBC) life span (approximately 120 days)
Pyuria
RBC transfusion

✓ **Type specific platelet transfusions:** Lorne Holland, MD at the University of Texas Southwestern Medical Center in Dallas wrote an article in the December 2006 issue of Lab Medicine. Even though platelets lack ABO and Rh antigens, their infusion products contain small amounts of red blood cell (RBC) antigens and serum antibodies. Certain patient groups should receive type specific platelet transfusions.

Small children – even a small amount of hemolysis from plasma antibodies can seriously affect their health.

Women of child bearing age – each platelet pack contains very small amounts of RBC antigen which, over time, can produce antibodies that would affect a fetus. Some

studies show as little as 0.03 mL cells can stimulate antibody production. A random donor platelet pack contains 0.30 to 0.59 mL red cells.

Persons needing long term replacement therapy – same long term effects with hemolysis and antibody build up.

All persons should have type specific product. When this is not possible, especially for young women, a dose of RhIG (known as RhoGam) should provide protection for up to 15 random donor platelet units.

✓ **Chemistry analyzer accuracy for serum versus plasma specimens:** Researchers in Taiwan compared serum to plasma samples on their chemistry analyzer. Their article, "Selected Analyte Values in Serum Versus Heparinized Plasma Using the SYNCHRON LX PRO Assay Methods/Instrument", appeared in the December 2006 issue of Lab Medicine. A study by Lum and Gambino was referenced. This article concludes there is no clinically significant difference between specimen types even though there may be a significant statistical difference. The Taiwan article states a slight medically significant difference for albumin and blood urea nitrogen on their instrument with Beckman reagents.

Remember, any time you vary from the manufacturer's instructions, the test becomes highly complex under CLIA regulations. This means extensive procedure validation and higher education/training for testing personnel.

✓ **Sink Testing:** No, that doesn't mean hold the urine over the sink before putting the dipstick in! It's a previous century phrase for reporting test results that were never performed. While most laboratory personnel would not consider such an unethical practice, some do. We know of at least one case in Utah. Other unethical practices could be just as serious to patient outcome as reporting results without testing. Consider the ethics of accepting results when controls were not in range or were expired. What about skipping new method validations or calibration verifications. Do you adjust standard curves to fit the data? Teach the value of ethical behavior to each new employee. Continue the teaching and talk about practices that might start a gradual slide down the unethical hill.

**Hepatitis C algorithm:** The Utah Public Health Laboratories performs Hepatitis C screening tests on the Axsym. They follow CDC's recommendations for confirmation testing. The Axsym reports the signal to cutoff ratio. Results <0.79 are reported non-reactive. Results between 0.80 and 1.21 are reported indeterminate and a new patient sample is recommended. Results above 1.21 are reported reactive.

The reactive group is further subdivided into low or high reactive. Low reactive values (1.21 to 10.0) require confirmatory testing. The assay, by design, is very sensitive (so no positive will be missed) making it more non-specific (false positives). This biological interference in ratio can be ruled out or infection with Hepatitis C determined by PCR or RIBA testing. High reactive values (>10.0) have a 95% chance of being diagnostic for disease.

Check the CDC website for complete guidelines and explanation: http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5203a1.htm.

## *FROM THE PATIENT'S CHART*

*"Large brown stool ambulating in the hall."*

# ☆ Feature ☆

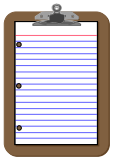
## LABORATORY TWINNING INITIATIVE

In November 2006 the Utah Public Health Laboratories (UPHL) received word from the World Health Organization (WHO) their "twinning" proposal was accepted. The UPHL is partnered with the Public Health Laboratory, Winston Scott Polyclinic, Barbados.

WHO's objective for this initiative is: "Within the International Health Regulations (IHR 2005), the objective of the laboratory twinning initiative is to contribute to the sustainable improvement of public health laboratory services in developing countries through establishing partnerships between these laboratories and institutions (reputable public health or appropriate academic or research organizations) and linking these individual partnerships in a network."

This initiative will be funded by WHO for at least 3 years. The Barbados laboratory requested help in strengthening "our laboratory's capacity to immediately detect any epidemic threat and support the critical role of the Public Health Laboratory in national health policy and planning." They requested specific help in pathogen identification, disease monitoring and surveillance, public health related research, safety officer training, TB surveillance, an expanded STI program, identification of emerging and re-emerging infectious disease agents, air quality and water quality monitoring.

UPHL employees will visit the Barbados Lab the end of May 2007. This is an exciting venture for our laboratory. We look forward to an enduring exchange with Barbados. We expect the learning to go both ways.



## CLIA BITS

### ADDITIONAL WAIVED TESTS:

° LifeSign Status Mono (whole blood)

°Bayer Clinitek Status Urine Chemistry Analyzer (microalbumin)

°Inverness Medical BioStar Acceava Strep A, Mono II (whole blood), Clearview *H. pylori* Test (whole blood) and Clearview Strep A Exact II Dipstick

°Inverness BTNX Inc Rapid Response *H. pylori* Rapid Test Device

°Chembio HIV ½ STAT-PAK

°Wolfe Drug Testing RealityCheck Integrated Specimen Cup

°Drug Detection Devices Ltd. Multi-Drug Multi-Line Screeners Dip Drug Test With the Integrated Screeners AutoSplit KO Test Cup

°Polymer Technology Systems CardioChek PA Analyzer and CardioChek Analyzer

°Innovacon Integrated E-Z Split Key Cup II

°Roche Diagnostics CoaguChek XS PST

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Microbiology media update: CLIA no longer requires a facility to recheck sterility and fastidious organism growth checks for each batch of chocolate agar received. The laboratory must still document the acceptable appearance of the media upon receipt.

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COLA's deemed status with CMS was renewed for an additional 6 years with the addition of new standard requirements to their inspection program. Some of the new items to be implemented in June 2007 include: revised quality control requirements, increased attention to laboratory information systems (LIS), focus on quality assessment in all testing phases, and quality systems incorporation in all specialties.

Joint Commission also received continued deemed status from CMS.

**The individual requirements for these accreditation organizations may differ slightly from CLIA regulations but the rules used to assure quality testing must be as stringent or more so than CLIA's.**

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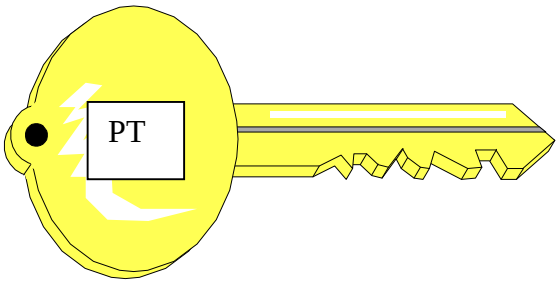
Each year CMS posts Federal Sanctions taken against laboratories in the Laboratory Registry. The registry for 2005 is now available on the CMS CLIA website (www.cms.hhs.gov/clia).

*Equals*

*"10 rations: 1 decoration"*




**Cytology Proficiency Testing**

ASCP published information on how slides will be chosen to meet CLIA proficiency testing (PT) requirements. All new slides will require at least 40 reads with a performance rating at 90% or better in the exact response category. The slide referee panel was expanded to include two cytotechnologists with the three pathologists. The panel will accept new slides only with 100% consensus from the 5 panelists. The Committee will continue to require blinded test slide reviews to help eliminate interpreter bias.

For more information on ASCP's cytology proficiency testing program go to www.ascp.org/ProficiencyTesting.

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Pennsylvania sent the first known PT samples to 59 laboratories who agreed to participate in the voluntary program in 1946. In 1967 the Clinical Laboratory Improvement Act mandated all laboratories participating in interstate commerce participate in PT. Finally in 1988 a CLIA amendment required all non-waived laboratories, wherever they were, successfully participate in PT for regulated analytes. Now PT is an integral part of everyday laboratory life.

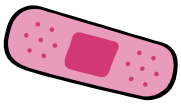
Clinical lab scientists from the American Proficiency Institute and Missouri State University wrote an article for the March 2007 issue of Lab Medicine entitled "Proficiency Testing: A guide to Maintaining Successful Performance". The authors gave 4 rules of Good Laboratory Practice to help achieve excellence in patient testing as well as PT performance.

1. Train the staff.
2. Use quality control (QC) ranges that will keep the instrument within the manufacturer's specified performance range.
3. Perform calibration verification at least as often as the manufacturer recommends – more often if you notice a shift or trend in QC or in PT peer performance review.
4. Follow any guidelines issued by scientific panels that come with your evaluations.

In addition, the authors recommend five practices that will help you avoid test errors.

A. Make certain you are assigned to the correct peer group for data analysis.
B. At the beginning of the year, mark the shipping dates on your calendar. Check to make certain the samples arrive in time.
C. Read the sample handling instructions as they can change on any testing event. Watch for clerical errors.
D. Report your answers by the due date. No late reports will be graded.
E. Review the standard deviation index (SDI) on the evaluation you receive. Statistical calculations are available in the article to help you decide when you need to investigate a trend before it becomes a PT failure.

Finally, the authors recommend any unsatisfactory score (80% to 99% for all tests except Immunohematology & HIV which require 100% to pass) be investigated before a potential serious problem is overlooked. The next time you could receive a 60% or worse. CLIA certification **requires** a documented investigation of any score less than 100%.



## SAFETY

### Hazardous Waste – Are You Contributing?

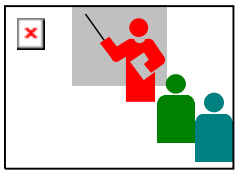
The top five hazardous waste violations cited by the Environmental Protection Agency (EPA) in 2006 were:

- Failure to determine a waste was classified as hazardous.
- Pouring hazardous waste down the drain.
- Waste containers not properly labeled.
- No documented staff training.
- Failure to produce or retain hazardous waste manifests.

Ponderables:

Since bread is square, why is sandwich meat round?

## CONTINUING EDUCATION



### New NLTN Programs

DPDx Parasitology Telediagnosis Assistance: What is it and what can it do for me? CDC - CD format.

Lab Safety in the Era of Bioterrorism. CDC - CD Power Point presentation for trainers.

Biosafety in Microbiological and Biomedical Laboratories - 4th Edition. CDC - CD with revised Appendix F.

## Understanding Our Universe

"I'm astounded by people who want to 'know' the universe when it's hard enough to find your way around Chinatown"
Woody Allen